Claim 15 was objected to for a minor informality. Accordingly, Applicants have amended the claim to correct the minor deficiency.

Claims 1, 2, 4, 5, 7, 8, 9, 11, 12 and 14 were rejected under 35 U.S.C. § 112, second paragraph. Applicants have amended the claims to more particularly point out and distinctly claim the subject matter. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 1-16 were rejected as anticipated by U.S. Patent Number 5,516,781 to Morris et al. (Morris). This rejection is respectfully traversed.

Morris discloses a method for preventing or treating hyperproliferative vascular disease in a mammal by administering an effective amount of an anti-proliferative (rapamycin) alone or in combination with mycophenolic acid. The delivery method may include the use of a stent. Specifically, Morris discloses the use of rapamycin in preventing smooth muscle cell hyperplasia, restenosis and vascular occlusion resulting from mechanically mediated injury.

Anticipation exists only if all of the elements of the claimed invention are present in a system or method disclosed, expressly or inherently, in a single prior art reference. Therefore, if it can be shown that there is <u>one difference</u> between the claimed invention and what is disclosed in the single reference, there can be no anticipation.

The present invention, as claimed in amended independent claim 1, is directed to a method for preventing constrictive remodeling comprising a controlled delivery, by release from an intraluminal medical device, of an anti-proliferative/anti-inflammatory compound in therapeutic dosage amounts, the compound substantially reducing in-lesion lumen loss both proximate and distal to the intraluminal medical device. The present invention, as claimed in amended claim 8, is directed to a drug delivery device. The device comprises an intraluminal medical device and a therapeutic dosage of an anti-proliferative/anti-inflammatory agent releasably affixed to the intraluminal medical device for the treatment of constrictive vascular remodeling. The agent substantially reducing in-lesion lumen loss both proximal and distal to the intraluminal medical device.

Morris does not address a method or device for the prevention of vascular remodeling. Morris does not address a method or device wherein an anti-proliferative/anti-inflammatory agent is released from a device for substantially reducing in-lesion lumen loss both proximal and distal to the intraluminal medical device. Since Morris does not address these elements, there can be no anticipation. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 1-16 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application Number 09/850,233, claims 1-15 of, copending Application Number 09/850,507, claims 1-17 of copending Application Number

09/850,232, claims 1-14 of copending Application Number 09/850,365 and claims 1-15 of copending Application Number 09/575,480.

Applicants understand that these rejections are to alert Applicants that an actual rejection on the same ground may be issued if one of the applications ultimately issues. However, in light of the amendments to the claims of the present invention and any potential amendments made to the claims of the cited applications, Applicants shall defer any arguments and/or actions until the applications actually issue.

Applicants would be willing to interview the present case if the Examiner so desires. Accordingly, the Examiner is invited to call the undersigned at (732) 524-2518 if such a call would facilitate the prosecution of this application.

A favorable action on the merits is earnestly solicited.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached pages are captioned "Version With Markings To Show Changes Made."

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS

Please amend the claims as follows:

1. (Amended) A method for [the prevention of] preventing constrictive remodeling comprising [the]a controlled delivery, by release from an intraluminal medical device, of [a]an anti-proliferative/anti-inflammatory compound in therapeutic dosage amounts, the compound substantially reducing in-lesion lumen loss both proximate and distal to the intraluminal medical device.

2. (Amended) The method for [the prevention of]preventing constrictive remodeling according to Claim 1, further includes utilizing the compound to block [the]a proliferation of fibroblasts in [the]a vascular wall in response to injury, thereby reducing [the]a formation of vascular scar tissue.

3. (Amended) The method for [the prevention of]preventing constrictive remodeling according to Claim 2, wherein the compound comprises rapamycin.

4. (Amended) The method for [the prevention of]preventing constrictive remodeling according to Claim 2, wherein the compound comprises analogs and congeners that bind a high-affinity cytosolic protein, FKBP12, and possesses [the same] pharmacologic properties [as]equivalent to rapamycin.

5. (Amended) The method for [the prevention of]preventing constrictive remodeling according to Claim 1, further includes utilizing the compound to affect [the]a translation of certain proteins involved in [the]a collagen formation or metabolism.

6. (Amended) The method for [the prevention of]preventing constrictive remodeling according to Claim 5, wherein the compound comprises rapamycin.

7. (Amended) The method for [the prevention of]preventing constrictive remodeling according to Claim 5, wherein the compound comprises analogs and congeners that bind a high-affinity cytosolic protein, FKBP12, and possesses [the same] pharmacologic properties [as]equivalent to rapamycin.

8. (Amended) A drug delivery device comprising:

an intraluminal medical device; and

a therapeutic dosage of an anti-proliferative/anti-inflammatory agent releasably affixed to the intraluminal medical device for [the] treatment of constrictive vascular remodeling, the agent substantially reducing in-lesion lumen loss both proximal and distal to the intraluminal medical device.

9. (Amended) The drug delivery device according to Claim 8, wherein the agent blocks [the]a proliferation of fibroblasts

in [the]a vascular wall in response to injury, thereby reducing [the]a formation of vascular scar tissue.

11. (Amended) The drug delivery device according to Claim 9, wherein the agent comprises analogs and congeners that bind a high-affinity cytosolic protein, FKBP12, and possesses [the same] pharmacologic properties [as]equivalent to rapamycin.

12. (Amended) The drug delivery device according to Claim 8, wherein the agent affects the translation of certain proteins involved in [the] collagen formation or metabolism.

14. (Amended) The drug delivery device according to Claim 12, wherein the agent comprises analogs and congeners that bind a high-affinity cytosolic protein, FKBP12, and possesses [the same] pharmacologic properties [as]equivalent to rapamycin.

15. (Amended) The drug delivery device according to Claim 8, wherein [thee]the intraluminal medical device comprises a stent.